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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/536,827	10/31/2005	Ken Inose	0666.2520000/TGD/AFK	7957	
26111 7590 6605/2009 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W.			EXAM	EXAMINER	
			SIEFKE, SAMUEL P		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/536,827 INOSE ET AL. Office Action Summary Examiner Art Unit SAM P. SIEFKE 1797 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 21 January 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-18 is/are pending in the application. 4a) Of the above claim(s) 18 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-17 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/S5/08)
Paper No(s)/Mail Date \_\_\_\_\_\_\_.

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5 Notice of Informal Patent Application

### DETAILED ACTION

### Election/Restrictions

Newly submitted claim 18 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 18 is directed to a the subcombination, the subcombination can be used for electrophoresis of a sample. The combination does not require the particulars of the subcombination in that the combination can be employed for sample preparation in setting up serial dilutions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 18 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

# Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not Application/Control Number: 10/536,827

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Valve 10 is the only valve in the specification. Claim 6 recites valves (plural) but the specification is silent on a plurality of valves and the wash storage, elute storage and the discharge portion are joined to the passage through the respective valve.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6.391,541 to Petersen et al.

Regarding claims 1 and 2, Petersen teaches a device for pretreating a specimen comprising a single base (FIG. 1, bottom piece 26), a specimen introducing portion capable of liberating a nucleic acid from the specimen (FIG. 3, inlet port 64); a holding portion for holding the nucleic acid (FIG. 3 sample chamber 65 for holding a fluid); a wash storage (FIG. 3, wash chamber 66); an elute storage (FIG. 7, reagent chamber 67); a discharging portion for discharging liquid (FIG. 3, waste chamber 68); wherein the specimen introducing portion, the holding portion, the wash storage, the elute storage,

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and the discharging portion are provided together on the single base (cartridge 24 containing all the components on base 28); an extraction portion (abstract and cartridge); a vertical circuit passage (figure 7 passageways connecting the above chambers).

Regarding claims 3, Petersen teaches a device for pretreating a specimen comprising a single base (FIG. 1, bottom piece 26), a specimen introducing portion capable of liberating a nucleic acid from the specimen (FIG. 3, inlet port 64); a holding portion for holding the nucleic acid (FIG. 3 sample chamber 65 for holding a fluid); a discharging portion for discharging a wash (FIG. 3, waste chamber 68 for receiving used wash solution); an extracting portion for extracting the nucleic acid (FIG. 2, reaction vessel 42); grooves provided on the base (various channels, col. 5 lines 46-49), wherein on the base, the holding portion is connected through the grooves to the specimen introducing portion, the discharging portion and the extracting portion, respectively (FIG. 4 shows on cartridge 24, various channels or grooves connecting the holding portion, specimen introducing portion, discharging portion and extracting portion).

Regarding claim 4, Petersen teaches a device for pretreating a specimen comprising a single base (FIG. 1, bottom piece 26), a specimen introducing portion capable of liberating a nucleic acid from the specimen (FIG. 3, inlet port 64); a holding portion for holding the nucleic acid (FIG. 3 sample chamber 65 for holding a fluid); a discharging portion for discharging a wash (FIG. 3, waste chamber 68 for receiving used wash solution); and wherein the specimen introducing portion, the holding portion,

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the extracting portion, and the discharging portion are provided together on the base (cartridge 24 on base 28). Petersen teaches an air pump (pneumatic pump, col. 6 lines 9-10); connectors connected to the air pump (pressure nozzle, col. 16 line 8); wherein the extracting portion and the discharging portion are connected through the respective connectors to the air pump (col. 15, lines 66-67 to col. 16 line 1), and capable of inhaling air from the connectors so as to control a movement of the liquid on the base (col. 16 lines 11-17).

## Response to Arguments

Applicant's arguments filed 1/21/09 have been fully considered but they are not persuasive. Applicant argues, "the wash and reagent chambers 66 and 67 are not joined to a vertically intermediate portion of the passage, as provided by amended claim 1." The wash and reagent chambers 66 and 67 are joined to a vertically intermediate portion of the passage as seen in figure 4, middle section 24, passage that connects the was and reagent chamber. Regarding the vertical limitation, it is the Examiner's position that vertical is relationship that has be given a relative position, i.e. vertical from the base. Since the Applicant has not given a vertical a relationship to a position or physical structure the Examiner interprets the passage way connecting the wash and reagent chambers being vertical in that wash chamber is located vertically above the reagent chamber as seen in figure 3.

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#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/ Primary Examiner, Art Unit 1797